

IFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 3766

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Signature

Date of Signature

Elizabeth Eiche
July 19, 2006

Patent Application of

Michael R.S. Hill

Application No. 10/657,353

Confirmation No.: 1650

Filed: September 8, 2003

Examiner: Frances P. Oropeza

"METHOD AND SYSTEM FOR
DELIVERY OF VASOACTIVE DRUGS
TO THE HEART PRIOR TO AND
DURING A MEDICAL PROCEDURE"

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §1.97(b)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08A and/or PTO/SB/08B. Copies of non-U.S. patent and foreign references are attached.

Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

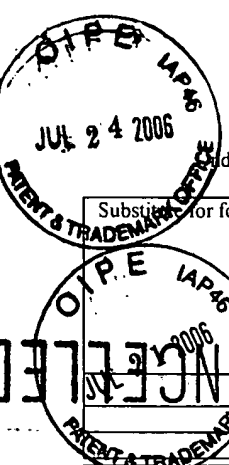
Raye Lynn Daugherty

Raye L. Daugherty
Reg. No. 47,933

File No. 065071-9060-02
Michael Best & Friedrich LLP
100 East Wisconsin Avenue
Suite 3300
Milwaukee, Wisconsin 53202-4108
414.271.6560

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Substitution for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 11

Complete if Known

Application Number	10/657,353
Filing Date	September 8, 2003
First named Inventor	Michael R.S. Hill
Group Art Unit	3766
Examiner name	Frances P. Oropeza
Attorney Docket Number	065071-9060-02

U.S. Patent Documents

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	3,614,995	Probert, et al.	10/26/1971
	3,804,098	Freidman	4/16/1974
	3,937,226	Funke	2/10/1976
	4,088,138	Diack, et al.	5/9/1978
	4,088,140	Fritsche	2/15/1977
	4,161,952	Kinney et al.	7/24/1979
	4,176,660	Mylrea, et al.	12/4/1979
	4,198,963	Barkalow, et al.	4/22/1979
	4,303,075	Heilman et al.	12/1/1981
	4,304,239	Perlin	12/8/1981
	4,321,929	Lemelson et al.	3/30/1982
	4,332,259	McCorkle, Jr.	6/1/1982
	4,351,330	Scarberry	9/28/1982
	4,354,497	Kahn	10/19/1982
	4,458,677	McCorkle, Jr.	7/10/1984
	4,548,203	Tacker, Jr. et al.	10/22/1985
	4,574,807	Hewson et al.	3/11/1986
	4,603,705	Speicher, et al.	8/5/1986
	4,640,298	Pless et al.	2/3/1987
	4,671,295	Abrams et al.	6/9/1987
	4,715,367	Crossley	12/29/1987
	4,722,347	Abrams	2/2/1988

Examiner
SignatureDate
Considered

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 2 of 11		Complete if Known		
		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		4,753,244	Landymore et al.	6/29/1988
		4,919,147	Reinhardt, et al.	4/24/1990
		4,928,688	Mower	5/29/1990
		4,929,688	Allen et al.	5/29/1990
		4,931,464	Grover et al.	6/5/1990
		4,952,586	Morris et al.	8/28/1990
		4,960,133	Hewson	10/2/1990
		5,003,991	Takayama, et al.	4/2/1991
		5,007,893	Row	4/16/1991
		5,014,698	Cohen	5/14/1991
		5,024,228	Goldstone et al.	6/18/1991
		5,025,807	Zabara	6/25/1991
		5,036,848	Hewson	8/6/1991
		5,044,367	Endres et al.	9/3/1991
		5,050,600	Parks	9/24/1991
		5,052,390	Hewson	10/1/1991
		5,056,519	Vince	10/15/1991
		5,056,532	Hull et al.	10/15/1991
		5,117,882	Laghi	6/2/1992
		5,117,828	Metzger et al.	6/2/1992
		5,125,406	Goldstone et al.	6/30/1992
		5,127,407	Tan	7/7/1992
		5,129,392	Bardy et al.	7/14/1992
Examiner Signature			Date Considered	

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		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,154,172	Terry, Jr. et al.	10/13/1992
		5,156,149	Hudrlik	10/20/1992
		5,156,151	Imran	10/20/1992
		5,174,289	Cohen	12/29/1992
		5,178,149	Imburgia, et al.	1/12/1993
		5,179,950	Stanislaw	1/19/1993
		5,179,952	Buinevicius et al.	1/19/1993
		5,186,170	Varrichio et al.	2/16/1993
		5,188,104	Wernicke et al.	2/23/1993
		5,191,885	Bilof, et al.	3/9/1993
		5,199,428	Obel et al.	4/6/1993
		5,203,326	Collins	4/20/1993
		5,205,285	Baker, Jr.	4/27/1993
		5,215,086	Terry, Jr. et al.	6/1/1993
		5,231,988	Wernicke et al.	8/3/1993
		5,235,980	Varrichio et al.	8/17/1993
		5,243,980	Mehra	9/14/1993
		5,263,480	Wernicke et al.	12/14/1993
		5,265,603	Hudrlik	11/30/1993
		5,265,623	Kroll, et al.	11/30/1993
		5,267,560	Cohen	12/7/1993
		5,269,303	Wernicke et al.	12/14/1993
		5,282,468	Klepinski	2/1/1994
Examiner Signature			Date Considered	

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		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,284,146	Czar et al.	2/8/1994
		5,292,338	Bardy	3/8/1994
		5,299,569	Wernicke et al.	4/5/1994
		5,304,120	Crandell et al.	4/19/1994
		5,304,206	Baker, Jr. et al.	4/19/1994
		5,304,220	Maginot	4/19/1994
		5,330,507	Schwartz	7/19/1994
		5,330,515	Rutecki et al.	7/19/1994
		5,334,221	Bardy	8/2/1994
		5,335,657	Terry, Jr. et al.	8/9/1994
		5,354,318	Taepke	10/11/1994
		5,356,425	Bardy et al.	10/18/1994
		5,365,926	Desai	11/22/1994
		5,379,765	Kajiwara et al.	1/10/1995
		5,403,356	Hill et al.	4/4/1995
		5,411,529	Hudrlik	5/2/1995
		5,417,713	Cohen	5/23/1995
		5,456,254	Pietroski et al.	10/10/ 1995
		5,458,625	Kendall	10/17/1995
		5,476,485	Weinberg, et al.	12/19/1995
		5,501,702	Plicchi et al.	3/26/1996
		5,501,703	Holsheimer et al.	3/26/1996
		5,507,784	Hill et al.	4/16/1996
Examiner Signature			Date Considered	

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 5 of 11		Complete if Known	
		Application Number	10/657,353
		Filing Date	September 8, 2003
		First named Inventor	Michael R.S. Hill
		Group Art Unit	3766
		Examiner name	Frances P. Oropeza
		Attorney Docket Number	065071-9060-02
U.S. Patent Documents			
Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	5,514,161	Limousin	5/7/1996
	5,531,776	Ward et al.	7/2/1996
	5,540,730	Terry, Jr.	7/30/1996
	5,540,732	Testerman	7/30/1996
	5,549,655	Erickson	8/27/1996
	5,571,150	Wernicke et al.	11/5/1996
	5,578,061	Stroetmann et al.	11/26/1996
	5,584,867	Limousin	12/17/1996
	5,611,350	John	3/18/1997
	5,620,468	Mongeon et al.	4/15/1997
	5,651,378	Matheny et al.	7/29/1997
	5,656,420	Chien	8/12/1997
	5,662,689	Elsberry, et al.	9/2/1997
	5,668,117	Shapiro	9/16/1997
	5,690,681	Geddes et al.	11/25/1997
	5,674,259	Gray	10/7/1997
	5,700,282	Zabara	12/23/1997
	5,707,400	Terry, Jr. et al.	1/13/1998
	5,713,924	Min et al.	2/3/1998
	5,713,929	Hess et al.	2/3/1998
	5,720,768	Verboven-Nelissen	2/24/1998
	5,755,682	Knudson, et al.	5/26/1998
	5,782,874	Loos	7/21/1998
Examiner Signature		Date Considered	

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 5 of 11		Complete if Known		
		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,514,161	Limousin	5/7/1996
		5,531,776	Ward et al.	7/2/1996
		5,540,730	Terry, Jr.	7/30/1996
		5,540,732	Testerman	7/30/1996
		5,549,655	Erickson	8/27/1996
		5,571,150	Wernicke et al.	11/5/1996
		5,578,061	Stroetmann et al.	11/26/1996
		5,584,867	Limousin	12/17/1996
		5,611,350	John	3/18/1997
		5,620,468	Mongeon et al.	4/15/1997
		5,651,378	Matheny et al.	7/29/1997
		5,656,420	Chien	8/12/1997
		5,662,689	Elsberry, et al.	9/2/1997
		5,668,117	Shapiro	9/16/1997
		5,690,681	Geddes et al.	11/25/1997
		5,674,259	Gray	10/7/1997
		5,700,282	Zabara	12/23/1997
		5,707,400	Terry, Jr. et al.	1/13/1998
		5,713,924	Min et al.	2/3/1998
		5,713,929	Hess et al.	2/3/1998
		5,720,768	Verboven-Nelissen	2/24/1998
		5,755,682	Knudson, et al.	5/26/1998
		5,782,874	Loos	7/21/1998
Examiner Signature			Date Considered	

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 6 of 11		Complete if Known		
		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,791,187	Chang	8/11/1998
		5,792,187	Adams	8/11/1998
		5,792,203	Schroeppel	8/11/1998
		5,797,970	Pouvreau	8/25/1998
		5,799,661	Boyd, et al.	9/1/1998
		5,824,021	Rise	10/20/1998
		5,836,994	Bourgeois	11/17/1998
		5,840,076	Swanson et al.	11/24/1998
		5,846,263	Peterson et al.	12/8/1998
		5,846,264	Andersson et al.	12/8/1998
		5,874,420	Pelleg	2/23/1999
		5,889,033	Kaminski	3/30/1999
		5,893,881	Elsberry et al.	4/13/1999
		5,893,882	Peterson, et al.	4/13/1999
		5,902,324	Thompson et al.	5/11/1999
		5,913,876	Taylor et al.	6/22/1999
		5,916,239	Geddes et al.	6/29/1999
		5,928,272	Adkins, et al.	7/27/1999
		5,964,789	Karsdon	10/12/1999
		5,971,911	Wilk	10/26/1999
		5,977,408	Levin et al.	11/2/1999
		5,995,872	Bourgeois	11/30/1999
		5,998,386	Feldman	12/7/1999
Examiner Signature			Date Considered	

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 7 of 11		Complete if Known		
		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		6,006,134	Hill et al.	12/21/1999
		6,007,559	Arkans	12/28/1999
		6,014,588	Fitz	12/7/1999
		6,042,538	Puskas	3/28/2000
		6,043,273	Duhaylongsod	3/28/2000
		6,060,454	Duhaylongsod	5/9/2000
		6,073,048	Kieval, et al.	6/6/2000
		6,087,394	Duhaylongsod	7/11/2000
		6,091,988	Warman et al.	7/18/2000
		6,101,412	Duhaylongsod	8/8/2000
		6,103,722	Schultz, et al.	8/15/2000
		6,127,410	Duhaylongsod	10/3/2000
		6,141,589	Duhaylongsod	10/31/2000
		6,141,590	Renirie et al.	10/31/2000
		6,184,239	Puskas	2/6/2001
		6,185,459	Mehra et al.	2/6/2001
		6,221,851	Feldman	4/2/2001
		6,234,985	Lurie et al.	5/22/2001
		6,253,108	Rosborough, et al.	6/26/2001
		6,266,564	Hill et al.	7/24/2001
		6,272,380	Warman et al.	8/7/2001
		6,299,564	Gessler et al.	10/9/2001
		6,303,293	Patterson et al.	10/16/2001
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		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		6,304,777	Ben-Haim, et al.	10/16/2001
		6,381,499	Taylor et al.	4/30/2002
		6,414,018	Duhaylongsod	7/2/2002
		6,429,217	Puskas	8/6/2002
		6,442,429	Hill et al.	8/27/2002
		6,449,507	Hill et al.	9/10/2002
		6,473,644	Terry, Jr. et al.	10/29/2002
		6,479,523	Puskas	11/12/2002
		6,487,446	Hill et al.	11/26/2002
		6,532,388	Hill et al.	3/11/2003
		6,537,540	Burnstein et al.	3/25/2003
		6,542,774	Hill et al.	4/1/2003
		6,554,781	Carter et al.	4/29/2003
		6,572,895	Smith et al.	6/3/2003
		6,587,719	Barrett et al.	7/1/2003
		6,589,954	Mavunkel et al.	7/8/2003
		6,609,025	Barrett et al.	8/19/2003
		6,622,038	Barrett et al.	9/16/2003
		6,622,041	Terry, Jr. et al.	9/16/2003
		6,622,047	Barrett et al.	9/16/2003
		6,628,987	Hill et al.	9/30/2003
		6,656,960	Puskas	12/2/2003
		6,690,973	Hill et al.	2/10/2004
Examiner Signature			Date Considered	

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		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
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		Application Number	10/657,353	
		Filing Date	September 8, 2003	
		First named Inventor	Michael R.S. Hill	
		Group Art Unit	3766	
		Examiner name	Frances P. Oropeza	
		Attorney Docket Number	065071-9060-02	
U.S. Patent Documents				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
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Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
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	EP	1005337	Puskas	5/11/2005		
	EP	1181947	Borkan	2/27/2002		
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	MX	2043	Puskas	8/26/1998		
	WO	97/40885	Jonkman	11/6/1997		

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				Filing Date		September 8, 2003	
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				Group Art Unit		3766	
				Examiner name		Frances P. Oropeza	
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FOREIGN PATENT DOCUMENTS							
Examiner Initials		Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
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		WO	01/00273	Puskas	6/23/2000		
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		WO	99/09971	Puskas	3/4/1999		
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		WO	99/63926	Lurie et al.	12/16/1999		
		WO	00/09206	Mehra et al.	2/24/2000		

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				Filing Date	September 8, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Frances P. Oropeza
Sheet	1	of	10	Attorney Docket Number	065071-9060-02

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		AGNEW, William F., et al., "Considerations for Safety with Chronically Implanted Nerve Electrodes, Epilepsia, 31(Suppl. 2), 1990, pp. S27-S32, Raven Press, Ltd., New York.
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				Application Number	10/657,353
				Filing Date	September 8, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Frances P. Oropeza
Sheet	2	of	10	Attorney Docket Number	065071-9060-02

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		BLUEMEL, K.M., et al., "Parasympathetic Postganglionic Pathways to the Sinoatrial Node," Am. Phys. Soc., 1990, pp. H1504-H1508.
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				Filing Date	September 8, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Frances P. Oropeza
Sheet	3	of	10	Attorney Docket Number	065071-9060-02

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		Declaration/Clarification of John D. Puskas, MD., dated October 11, 2005, pp. 1-7.
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		GAYKEMA, R., et al., "Subdiaphragmatic Vagotomy Suppresses Endotoxin-Induced Activation of Hypothalamic Corticotropin-releasing Hormone Neurons and ACTH Secretion," Endocrinology, Vol. 136, No. 10, pp. 4717-4720, 1995.
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Sheet	5	of	10	Attorney Docket Number	065071-9060-02

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		KHANNA, R., et al., "Coronary Artery Surgery With Induced Temporary Asystole and Intermittent Ventricular Pacing: An Experimental Study," Cardiovascular Surgery, Vol. 4, No. 2, pp. 231-236 (1996)
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				Examiner Name	Frances P. Oropeza
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		MALONEY, R., et al., "A New Method for Intraoperative Recurrent Laryngeal Nerve Monitoring," ENT Journal, 1994, Vol. 73, No. 1, pp. 30-33.
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				Application Number	10/657,353
				Filing Date	September 8, 2003
				First Named Inventor	Michael R.S. Hill
				Group Art Unit	3766
				Examiner Name	Frances P. Oropeza
Sheet	7	of	10	Attorney Docket Number	065071-9060-02

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Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		NOONAN, DAVID, "And the Beat Goes On," <u>Newsweek</u> , July 11, 2005, pp. 56-57.
		OKAZAWA, M., et al., "Effect of Vagal Stimulation and Parenteral Acetylcholine on Canine Trachealis Muscle Shortening," J. Appl. Physiol., Vol. 75, No. 6, pp. 2463-2468, 1992 (Abstract Only).
		PACE, (on the use of nerve cuff stimulation of the vagal nerves, October 1992, Vol. 15, No. 10, pt. 11, pp. 1543-1630.
		PENRY, J. Kiffin, et al., "Prevention of Intractable Partial Seizures by Intermittent Vagal Stimulation in Humans: Preliminary Results," Epilepsia, 31(Suppl. 2), 1990, pp. S40-S43, Raven Press, Ltd., New York.
		PFISTER, et al., "Coronary Artery Bypass Without Cardiopulmonary Bypass," Ann. Thorac. Surg., 54:1085-92.
		POLLER, U., et al., "Age-Dependent Changes in Cardiac Muscarinic Receptor Function in Healthy Volunteers," JACC Vol. 29, No. 1, 1997: 187-93.
		RAMSAY, R., et al., "Vagus Nerve Stimulation for Treatment of Partial Seizures: 2. Safety, Side Effects, and Tolerability," Epilepsia, 35(3): 627-636, 1994.
		RANDALL, Walter C., PhD., "Parasympathetic Control of the Heart," Chapter 4, Nervous Control of Cardiovascular Function, 1984, pp. 68-94.
		RANDALL, Walter C., Ph.D. et al., "Functional Anatomy of the Cardiac Efferent Innervation," Neurocardiology, 1988, pp. 3-24.

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		REID, Steven A., "Surgical Technique for Implantation of the Neurocybernetic Prosthesis," Epilepsia, 1990, 31 (suppl. 2): S38-S39.
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		THOMPSON, et al., "Bradycardia Induced by Intravascular Versus Direct Stimulation of the Vagus Nerve," Ann. Thorac. Surg., 1998; 65: 637-42.
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		YOKOYAMA, T., et al., "Tumor Necrosis Factor - α Provokes a Hypertrophic Growth Response in Adult Cardiac Myocytes," Circulation, Vol. 95, pp. 1247-1252, 1997.

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